

LACTATED RINGERS - sodium chloride, sodium lactate, potassium chloride and calcium chloride injection, solution
Baxter Healthcare Corporation

DESCRIPTION

Lactated Ringer's Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment in single dose containers for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1.

Table 1

	Size (mL)	Composition (g/L)				Osmolarity (mOsm/L) (calc)	pH nominal (range)	Ionic Concentration (mEq/L)					Caloric Content (kcal/L)
		Sodium Chloride, USP (NaCl)	Sodium Lactate, USP (C ₃ H ₅ NaO ₃)	Potassium Chloride, USP (KCl)	Calcium Chloride, USP (CaCl ₂ ·2H ₂ O)			Sodium	Potassium	Calcium	Chloride	Lactate	
Lactated Ringer's Injection, USP	250	6	3.1	0.3	0.2	273	6.5 (6.0 to 7.5)	130	4	2.7	109	28	9
	500												
	1000												

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See DIRECTIONS FOR USE). The primary function of the overwrap is to protect the container from the physical environment.

CLINICAL PHARMACOLOGY

Lactated Ringer's Injection, USP has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

Lactated Ringer's Injection, USP produces a metabolic alkalizing effect. Lactate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

INDICATIONS AND USAGE

Lactated Ringer's Injection, USP is indicated as a source of water and electrolytes or as an alkalizing agent.

CONTRAINDICATIONS

None known

WARNINGS

Lactated Ringer's Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

Lactated Ringer's Injection, USP should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

Lactated Ringer's Injection, USP should be used with great care in patients with metabolic or respiratory alkalosis. The administration of lactate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

Lactated Ringer's Injection, USP should not be administered simultaneously with blood through the same administration set because of the likelihood of coagulation.

The intravenous administration of Lactated Ringer's Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely

proportional to the electrolyte concentrations of the injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections.

In patients with diminished renal function, administration of Lactated Ringer's Injection, USP may result in sodium or potassium retention.

Lactated Ringer's Injection, USP is not for use in the treatment of lactic acidosis.

PRECAUTIONS

General

Do not connect flexible plastic containers of intravenous solutions in series connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Lactated Ringer's Injection, USP must be used with caution. Excess administration may result in metabolic alkalosis.

Laboratory tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of Lactated Ringer's Injection, USP to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Lactated Ringer's Injection, USP.

Carcinogenesis, mutagenesis, impairment of fertility

Studies with Lactated Ringer's Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C

Animal reproduction studies have not been conducted with Lactated Ringer's Injection, USP. It is also not known whether Lactated Ringer's Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Lactated Ringer's Injection, USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of Lactated Ringer's Injection, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Lactated Ringer's Injection, USP is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of Lactated Ringer's Injection, USP in pediatric patients have not been established by adequate and well controlled trials, however, the use of electrolyte solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

Geriatric Use

Clinical studies of Lactated Ringer's Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

ADVERSE REACTIONS

Allergic reactions or anaphylactoid symptoms such as localized or generalized urticaria and pruritis; periorbital, facial, and/or laryngeal edema; coughing, sneezing, and/or difficulty with breathing have been reported during administration of Lactated Ringer's Injection, USP. The reporting frequency of these signs and symptoms is higher in women during pregnancy.

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

DOSAGE AND ADMINISTRATION

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used.

Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

HOW SUPPLIED

Lactated Ringer's Injection, USP in AVIVA plastic container is available as follows:

Code	Size (mL)	NDC
6E2322	250	0338-6307-02
6E2323	500	0338-6307-03
6E2324	1000	0338-6307-04

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

DIRECTIONS FOR USE OF AVIVA PLASTIC CONTAINER

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.

3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

Baxter Healthcare Corporation

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Printed in USA

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PACKAGE LABEL - PRINCIPAL DISPLAY PANEL

Container Label

LOT

EXP

250 mL

6E2322
NDC 0338-6307-02

Lactated Ringer's Injection USP

50

100

EACH 100 mL CONTAINS 600 mg SODIUM
CHLORIDE USP 310 mg SODIUM LACTATE
30 mg POTASSIUM CHLORIDE USP
20 mg CALCIUM CHLORIDE USP pH 6.5 (6.0
TO 7.5) mEq/L SODIUM 130 POTASSIUM
4 CALCIUM 2.7 CHLORIDE 109 LACTATE
28 OSMOLARITY 273 mOsmol/L (CALC)
STERILE NONPYROGENIC SINGLE DOSE
CONTAINER **NOT FOR USE IN THE TREATMENT
OF LACTIC ACIDOSIS** ADDITIVES MAY BE
INCOMPATIBLE CONSULT WITH PHARMACIST
IF AVAILABLE WHEN INTRODUCING ADDITIVES
USE ASEPTIC TECHNIQUE MIX THOROUGHLY
DO NOT STORE DOSAGE INTRAVENOUSLY
AS DIRECTED BY A PHYSICIAN SEE DIRECTIONS
CAUTIONS SQUEEZE AND INSPECT INNER BAG
WHICH MAINTAINS PRODUCT STERILITY DISCARD
IF LEAKS ARE FOUND MUST NOT BE USED IN
SERIES CONNECTIONS DO NOT ADMINISTER
SIMULTANEOUSLY WITH BLOOD DO NOT USE
UNLESS SOLUTION IS CLEAR **Rx ONLY** STORE
AT ROOM TEMPERATURE (25°C/77°F) UNTIL
READY TO USE AVOID EXCESSIVE HEAT
SEE INSERT

150

200

Baxter

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA

BAXTER AVIVA AND THE AVIVA
CRESCENT DESIGN ARE TRADEMARKS OF
BAXTER INTERNATIONAL INC

FOR PRODUCT INFORMATION
1-800-933-0303

AVIVA CONTAINER



LOT

EXP

250 mL

6E2322

NDC 0338-6307-02

Lactated Ringer's

Injection USP

EACH 100 mL CONTAINS 600 mg SODIUM
CHLORIDE USP 310 mg SODIUM LACTATE

30 mg POTASSIUM CHLORIDE USP
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FOR PRODUCT INFORMATION

1-800-933-0303

AVIVA CONTAINER

Carton Label

6E2322

40-250 ML

AVIVA CONTAINER

LACTATED RINGER'S INJECTION, USP

EXP
XXXXX

SECONDARY BAR CODE

(17) YYMM00 (10) XXXXX

LOT
XXXXX

PRIMARY BAR CODE

(01) 50303386307028

6E2322
40-250 ML
AVIVA CONTAINER
LACTATED RINGER'S INJECTION, USP
EXP
XXXXX
SECONDARY BAR CODE
(17) YYMM00 (10) XXXXX
LOT
XXXXX
PRIMARY BAR CODE
(01) 50303386307028